# UNITED STATES DISTRICT COURT WESTERN DISTRICT OF MICHIGAN SOUTHERN DIVISION

Plaintiff,		
v.		Case No.
JAMES J. BERG, P.A.,		Hon.
Defendant.		
	/	

#### **COMPLAINT**

The United States of America, by its counsel, Andrew B. Birge, United States Attorney for the Western District of Michigan, and Andrew J. Hull and Ryan D. Cobb, Assistant United States Attorneys, states the following as its Complaint against the Defendant:

#### I. INTRODUCTION

- 1. This is an action to recover civil penalties and injunctive relief under the Controlled Substances Act ("CSA"), 21 U.S.C. §§ 801-971.
- 2. Defendant James J. Berg, P.A., maintains a license with the State of Michigan to practice as a physician assistant. Mr. Berg also maintains a controlled substance license with the State of Michigan. He previously maintained a controlled substance registration with the U.S. Drug Enforcement Administration ("DEA"), but surrendered his registration for cause on April 1, 2020.
- 3. As set forth more fully below, the United States contends that, from January 12, 2017, through November 20, 2019, Mr. Berg committed multiple violations of the Controlled Substances Act, 21 U.S.C. § 801 *et seq.*, as well as DEA's implementing regulations, by issuing prescriptions for controlled substances without a legitimate medical purpose and outside of the

usual course of professional practice.

#### II. JURISDICTION AND VENUE

- 4. The Court has jurisdiction pursuant to 21 U.S.C. §§ 842(c)(1), 843(f)(2), and 882(a), and 28 U.S.C. §§ 1331, 1345, and 1355(a).
- 5. Venue is appropriate in this District pursuant to 21 U.S.C. § 843(f)(2) and 28 U.S.C. §§ 1391(b)(1), 1391(b)(2), and 1395(a).

#### III. THE PARTIES

- 6. Plaintiff is the United States of America.
- 7. Defendant James J. Berg, P.A., is a resident of the State of Michigan. At all relevant times, he was licensed to practice as a physician assistant in Michigan and operated a pain management clinic, Hope Clinic for Muscle & Joint Pain, PLLC ("Hope Clinic"), in Traverse City in the Western District of Michigan.

#### IV. LEGAL BACKGROUND

#### A. The Controlled Substances Act

- 8. In 1970, Congress enacted the CSA based on a finding that "the illegal importation, manufacture, distribution, and possession and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people." 21 U.S.C. § 801(2).
- 9. The CSA and DEA's regulations categorize controlled substances into five schedules. Controlled substances listed in Schedule I have no accepted medical use in treatment and have a high potential for abuse and dependence. *See* 21 U.S.C. § 812. Controlled substances listed in Schedules II-V have some accepted medical use in treatment, but have varying potentials for abuse and dependence. *See id.* Schedule II controlled substances have the highest potential

for abuse and dependence, while Schedule V controlled substances have the least potential for abuse and dependence. *See id*.

- 10. Opioids belong to a class of drugs that can be used for medicinal purposes, primarily for the treatment of pain. Common prescription opioids include certain controlled substances listed in Schedule II such as oxycodone, hydrocodone, fentanyl, codeine, morphine, and methadone.
- 11. Benzodiazepines are a class of prescription drugs known as depressants that produce sedation, induce sleep, and relieve anxiety. Common prescription benzodiazepines include certain controlled substances listed in Schedule IV such as alprazolam, lorazepam, and oxazepam.
- 12. Due to certain dangers in concurrent prescribing of opioids and benzodiazepines, the Federal Food & Drug Administration ("FDA"), which regulates the labels and labeling of prescription drugs, requires manufacturers of opioids and benzodiazepines to include a "black box warning" on opioid and benzodiazepine drug labels, warning against simultaneous use of benzodiazepines and opioids, which may result in profound sedation, respiratory depression, coma, and death.
- 13. Carisoprodol is a muscle relaxer listed as a controlled substance in Schedule IV. The FDA drug label states that the drug should only be used for acute treatment periods up to two or three weeks, and, due to carisoprodol's sedative effects, it warns prescribers to exercise caution when a patient is also receiving prescriptions for opioids or benzodiazepines.
- 14. Carisoprodol can be used improperly to enhance the "euphoric" effects of other controlled substances, including opioids, benzodiazepines, and cocaine. For this reason, it is sought after by users who abuse opioids and benzodiazepines and is a highly diverted drug.

- 15. To prevent the diversion of controlled substances, the CSA regulates persons, companies, and other entities that manufacture, distribute, and dispense controlled substances.
- 16. The CSA authorizes DEA to regulate the distribution of controlled substances with the goal of creating a closed system of distribution under which all legitimate handlers of controlled substances—including manufacturers, distributors, practitioners, pharmacies, and researchers—must be registered with DEA and maintain strict accounting for all controlled substance distributions.
- 17. The closed system of distribution is intended to ensure that controlled substances only pass through legitimate channels and can be tracked from manufacturers to end users.
- 18. Compliance with DEA regulations, including the regulations governing the closed system of distribution, is essential to preventing the diversion of legally produced controlled substances into the illicit market.

# B. Registration

- 19. The CSA and DEA's regulations require those who handle controlled substances, other than the ultimate user, to obtain a controlled substance registration from DEA. Persons maintaining a controlled substance registration from DEA are referred to as "registrants."
- 20. Specifically, in order for a practitioner to prescribe or dispense a controlled substance, that practitioner must be registered with DEA for those activities.

# C. Requirements for Issuing a Prescription for a Controlled Substance

21. The CSA prohibits a registered prescriber from issuing an invalid prescription for a controlled substance. 21 U.S.C. §§ 829, 842(a)(1). In order for a prescription for a controlled substance to be valid, it must be issued for a legitimate medical purpose by a registered practitioner acting in the usual course of professional practice. 21 C.F.R. § 1306.04(a).

- 22. Whether a prescription for a controlled substance is issued for a legitimate medical purpose by a registered practitioner acting in the usual course of professional practice depends on a number of objective factors. To assist practitioners who, like Mr. Berg, use opioids to treat chronic pain, the Centers for Disease Control and Prevention developed national guidelines for prescribing opioids ("CDC Guidelines"). The CDC Guidelines are used as a standard throughout the country to help determine whether an opioid prescription is legitimate.
- 23. The CDC Guidelines formalize a number of objective criteria for considering whether to issue an opioid prescription. For example, the CDC Guidelines instruct that practitioners should prescribe the "lowest effective dosage," and should carefully reassess benefits and risks before increasing dosages to 50 or more morphine milligram equivalents ("MME") per day. The CDC Guidelines also warn practitioners to avoid dosages of 90 or more MME per day.
- 24. The CDC Guidelines further instruct practitioners to use urine drug testing before starting opioid therapy and to consider at least annual urine drug testing of patients in order to determine whether the patients are taking the medications as prescribed and whether they are using other non-prescribed controlled prescription drugs or illicit drugs.
- 25. The CDC Guidelines also warn that practitioners should avoid concurrent prescribing of opioids and benzodiazepines.
- 26. The Michigan Automated Prescription System ("MAPS") is a prescription monitoring program with a statewide database maintained by the Michigan Department of Health and Human Services. MAPS collects data to track prescription controlled substances, and prescribers and pharmacies use it to assess patient risk and prevent drug abuse and diversion.
- 27. As of June 1, 2018, prescribers in Michigan are required to obtain and review a MAPS report for a patient prior to prescribing that patient more than a three-day supply of

controlled substances. The prescriber should review the MAPS report to determine if the patient is obtaining controlled substances from another source (potentially engaging in "doctor shopping"), filling controlled substances at multiple pharmacies (potentially engaging in "pharmacy shopping"), or obtaining prescriptions for controlled substances that may negatively interact with what the prescriber is writing for the patient (e.g., combinations of opioids with benzodiazepines).

#### V. FACTS

- 28. At all relevant times, Mr. Berg was a physician assistant who co-owned and operated Hope Clinic, a pain management clinic, originally located at 2240 South Airport Road, Suite B, Traverse City, Michigan 49684 and subsequently located at 3221 Logan Valley Road, Traverse City, Michigan 49684.
- 29. Mr. Berg maintained a DEA controlled substance registration, No. MB2469408, by which he was authorized to prescribe and dispense controlled substances. Mr. Berg also maintained separate licensure with the State of Michigan to practice as a physician assistant and handle controlled substances.
- 30. As discussed in greater detail below, Mr. Berg required each of the patients he treated with opioid prescriptions to sign an opioid treatment agreement. Under these opioid treatment agreements, each patient agreed that:
  - Running out of medication early, needing early refills, and losing prescriptions may be signs of abuse of medication and reasons for Mr. Berg to stop prescribing;
  - Only Mr. Berg/Hope Clinic would prescribe the patient's opioids;
  - The patient would store medication in a safe and secure place, and that lost, stolen, or damaged medication will not be replaced;
  - The patient would inform Hope Clinic of all medications the patient is taking;
  - The patient would not drink alcohol or take mood-altering drugs (such as a

- benzodiazepine) when taking opioid medication because of the "significant risk for severe impairment or death"; and
- The patient would obtain all medications from one pharmacy.
- 31. From the start of Hope Clinic in 2014, Mr. Berg developed his own set of patients, and his unlawful prescribing activities for some of those patients are described below.
- 32. However, in September 2018, Mr. Berg also took on a new set of patients from Jonathan Robertson, D.O. Dr. Robertson was an osteopathic physician licensed to practice in Michigan. As part of his practice, Dr. Robertson treated a number of patients in Muskegon, Michigan, for chronic pain.
- 33. In September 2018, the Michigan Department of Licensing and Regulatory Affairs suspended Dr. Robertson's medical license for alleged criminal sexual conduct related to his prescribing of controlled substances, including providing controlled substances prescriptions to patients in exchange for sexual favors. That same month, the State of Michigan arrested and charged Dr. Robertson with criminal sexual conduct and numerous violations of state controlled substance laws, including improper prescribing of controlled substances. In December 2018, the Michigan Board of Osteopathic Medicine and Surgery revoked Dr. Robertson's license to practice medicine based on the alleged misconduct in the state's September 2018 summary suspension order.
- 34. Many of Dr. Robertson's patients were located in Muskegon, and he prescribed them high levels of opioids dangerously combined with carisoprodol.
- 35. Despite the numerous red flags surrounding these patients—including the arrest of, and allegations against, Dr. Robertson involving his prescribing behavior, the dangerous combinations of prescribed controlled substances (high doses of opioids combined with carisoprodol), and the fact that many of these patients were located approximately 130 miles away

in Muskegon—Mr. Berg took many of Dr. Robertson's former Muskegon patients into his own practice in September 2018.

- 36. As described in more detail below, from January 12, 2017, through November 20, 2019, Mr. Berg prescribed many of his patients high quantities of opioids and other controlled substances. In total, he prescribed over 1,300,000 dosage units of prescription opioids. Many of the controlled substance prescriptions Mr. Berg wrote were without a legitimate medical purpose and outside of the usual course of professional practice. These prescriptions were dangerously above the CDC Guidelines and Mr. Berg issued them despite multiple red flags indicating that the prescriptions were not legitimate. These red flags included patients traveling long distances, failing multiple urine drug tests, violating Hope Clinic's opioid treatment agreements, and displaying other conduct indicative of diversion. Additionally, Mr. Berg also frequently prescribed these opioids concurrent with other controlled substances, such as benzodiazepines and carisoprodol, resulting in dangerous combinations with risk of harm to patients.
- 37. Examples of Mr. Berg's illegitimate prescribing include, but are not limited to, the following:

#### A. <u>Patient P.P.</u>

38. P.P. was a forty-nine year old female patient referred to Hope Clinic for evaluation and treatment of pain. Her first visit with Mr. Berg occurred on March 9, 2017. A review of the MAPS report for P.P. for the last year, which Hope Clinic placed in P.P.'s patient file, revealed that P.P. was concurrently receiving high levels of opioids (fentanyl and oxycodone), at a daily average of 120 MME/day, with a benzodiazepine (alprazolam). The MAPS report also revealed that P.P. received controlled substance prescriptions from eleven different prescribers and filled the prescriptions at six different pharmacies. P.P.'s high MME daily dosage of opioids with the

dangerous concurrent prescribing of benzodiazepines were initial red flags that these prescriptions were not for a legitimate medical purpose, especially with the evidence that P.P. was engaged in both doctor and pharmacy shopping.

- 39. However, Mr. Berg's assessment after P.P.'s first visit was that P.P. had chronic pain requiring ongoing treatment with opioid pain medication, and he proceeded to continue to prescribe her opioids.
- 40. Another red flag occurred on March 15, 2017, when P.P. failed a urine drug test required by Hope Clinic by testing negative for the oxycodone she had previously been prescribed, indicating that P.P. was not taking the medication and was potentially diverting the opioids.
- 41. However, despite the failed urine drug test on March 15, 2017, Mr. Berg's patient notes for P.P.'s next visit on April 10, 2017, failed to address this anomaly, noting, instead, that there were "[n]o abnormal levels or red flags that would indicate inappropriate medication usage or metabolism have been seen with prior testing on 3-15-2017."
- 42. Another red flag occurred on November 16, 2017, when Hope Clinic staff learned that a local pharmacy refused to fill prescriptions for P.P. because she frequently sought early refills of controlled substances. Hope Clinic staff made a note of the discussion with the pharmacy, placing it in P.P.'s patient file. Hope Clinic also reviewed Mr. Berg's controlled substance prescriptions for P.P. against the dates of P.P's office visits, and noted that "we have been off" on prescribing refills.
- 43. Mr. Berg continued to prescribe P.P. high levels of opioids, increasing her dosage to 420 MME/day in December 2017, well above the CDC Guidelines.
- 44. Another red flag occurred when, on January 3, 2018, P.P. failed another urine drug test performed at Hope Clinic, once again testing negative for the oxycodone she was prescribed

and testing positive for a benzodiazepine (lorazepam) she was not prescribed, along with cough medicine and marijuana.

- 45. A MAPS report for P.P. contained in her patient file revealed that during the approximately twelve month period she was being seen by Mr. Berg, she had filled prescriptions for controlled substances at four different pharmacies, in violation of her opioid treatment agreement.
- 46. Despite the numerous red flags P.P. presented—high doses of opioids well over the CDC Guidelines, concurrent prescribing of benzodiazepines with opioids, evidence of doctor shopping and pharmacy shopping, multiple failed urine drug tests, early refills, and breach of her opioid treatment agreement—Mr. Berg continued to prescribe P.P. controlled substances, including the following prescriptions:

Written Date	Controlled Substance	Quantity
Jan. 29, 2018	Oxycodone Hcl 30 mg	120
Jan. 29, 2018	Fentanyl 50 MCG/Hr	10

Based on the unresolved red flags discussed above, Mr. Berg wrote each of these prescriptions without a legitimate medical purpose and outside of the usual course of professional practice. He continued over the next two years to write dozens of other controlled substance prescriptions for P.P. without a legitimate medical purpose and outside the usual course of professional practice. These prescriptions were filled at four different pharmacies, in violation of P.P.'s opioid treatment agreement with Hope Clinic. Additionally, many of these prescriptions constituted early refills. For example, Mr. Berg wrote 497-days worth of oxycodone between fill dates January 29, 2018, and April 8, 2019, resulting in an extra 62-day supply of oxycodone.

#### B. Patient T.H.

47. T.H. was a fifty-three year old female who first visited Mr. Berg at Hope Clinic on

- June 8, 2015. T.H. reported to Mr. Berg that she had been discharged from her former doctor's office for violating her pain management contract. Specifically, T.H. explained that she used up her prescribed hydrocodone "too quickly," and had failed a urine drug test by testing negative for the hydrocodone she was being prescribed, both red flags of patient misuse of opioids.
- 48. In the patient notes for T.H.'s first visit, however, Mr. Berg stated that he found "no evidence of abuse, diversion, doctor shopping, or addictive behaviors," and he prescribed her 180 pills of hydrocodone.
- 49. Less than two months after T.H.'s initial visit with Mr. Berg, T.H. failed a urine drug test on July 25, 2015, testing positive for both codeine and morphine—both Schedule II opioids—that she was not prescribed. This failed test started an alarming pattern of red flags that continued over the next several years.
- 50. On July 1, 2016, T.H. failed another urine drug test, this time testing negative for the hydrocodone Mr. Berg had prescribed her. This red flag was similar to the one the patient had reported to Mr. Berg as being the reason she was discharged from her prior prescriber.
- 51. On July 6, 2017, T.H. failed another urine drug test, testing negative for both the fentanyl and lorazepam Mr. Berg prescribed.
- 52. Then, on July 26, 2017, another red flag occurred when T.H. reported to Mr. Berg that her prescribed controlled substances had been stolen and that she required additional medication. Mr. Berg wrote T.H. prescriptions for additional fentanyl patches and oxycodone pills that she reported to the police as stolen, contrary to T.H.'s opioid treatment agreement. Mr. Berg also wrote T.H. a prescription for additional lorazepam pills, even though T.H. did not report that medication as stolen when she reported the purported theft to the police.
  - 53. Mr. Berg's first reference to T.H.'s repeated failed urine drug tests occurred in the

patient notes for a visit on August 31, 2017. However, he ignored the problems with the July 2015 and July 2016 tests, noting only that "[n]o abnormal levels or red flags that would indicate inappropriate medication usage or metabolism have been seen with prior testing on 7/2/2015 and 7-1-2016." And he failed to adequately address the issues with the failed July 2017 test, stating only that the test "was negative for Fentanyl and Ativan [lorazepam] but we did not verify patch placement and she believes it had been off for several days."

- 54. By December 18, 2017, Mr. Berg was prescribing T.H. dangerously high doses of opioids at over 487 MME/day. Along with these high doses of opioids, Mr. Berg was also prescribing T.H. concurrent doses of a benzodiazepine (lorazepam). Both the high doses of opioids and the dangerous concurrent prescribing of opioids with a benzodiazepine were contrary to the CDC Guidelines and raised red flags.
- 55. On January 18, 2018, another red flag occurred when T.H. failed another urine drug test, this time testing negative a second time for the lorazepam Mr. Berg prescribed. Mr. Berg never addressed this failed urine drug test in future patient notes.
- 56. On February 5, 2019, T.H. reported to Mr. Berg that her son had stolen her prescribed controlled substances. Similar to the reported theft incident from July 2017, this occurrence should have raised another red flag that the large quantities of controlled substances Mr. Berg prescribed T.H. were being diverted.
- 57. By April 2019, Mr. Berg was prescribing T.H. even higher doses of opioids, up to 585 MME/day.
- 58. Then, on May 10, 2019, an additional red flag occurred when T.H. reported to Mr. Berg during a patient visit that she had seen a different provider since her last visit at Hope Clinic and the other provider had placed her on buprenorphine, an opioid that can be used to treat opioid

use disorder and pain. That provider had taken T.H. off of the fentanyl and oxycodone Mr. Berg prescribed. However, at Hope Clinic, after he had failed to connect with this other provider, Mr. Berg placed T.H. back on the oxycodone and destroyed T.H.'s remaining buprenorphine pills. Buprenorphine is a dangerous controlled substance when prescribed concurrently with opioids.

- 59. Additionally, as of May 10, 2019, the MAPS report in T.H.'s patient file revealed that, during the two years prior, T.H. had obtained prescriptions for controlled substances from six separate pharmacies, in violation of her opioid treatment agreement.
- 60. Despite the multitude of red flags—high doses of opioids, concurrent prescribing of benzodiazepines, at least four failed urine drug screens, a history of violating opioid treatment agreements, multiple reported instances of diversion, dangerous prescribing of buprenorphine, and violation of Hope Clinic's own opioid treatment agreement—Mr. Berg continued to prescribe T.H. controlled substances, including the following prescriptions:

Written Date	Controlled Substance	Quantity
May 10, 2019	Oxycodone Hcl 30 mg	150
May 10, 2019	Lorazepam 0.5 mg	30
May 10, 2019	Oxycodone Hcl 30 mg	150
May 10, 2019	Lorazepam 0.5 mg	30
May 31, 2019	Fentanyl 12 MCG/Hr	10

Based on the unresolved red flags discussed above, Mr. Berg wrote each of these prescriptions without a legitimate medical purpose and outside of the usual course of professional practice.

#### C. Patient K.T.

- 61. K.T. was a thirty-five year old female patient from Muskegon when she first visited Mr. Berg at Hope Clinic on September 10, 2018, traveling approximately 260 miles roundtrip for this and subsequent appointments.
  - 62. Prior to visiting Mr. Berg, K.T. was a patient of Dr. Robertson, who had her on a

steady regimen of hydrocodone, methadone, and methylphenidate. At the time K.T. saw Mr. Berg, she was up to an opioid dosage of 214 MME/day, well above the CDC Guidelines.

- 63. Instead of performing an initial urine drug test for a new patient as prescribed by the CDC Guidelines, Mr. Berg initially kept K.T. on the same controlled substances prescribed by Dr. Robertson and did not perform any drug testing for several months.
- 64. When Mr. Berg did have K.T. take a urine drug test on January 3, 2019, K.T. immediately failed, testing positive for cocaine, a significant red flag.
- 65. On January 18, 2019, Mr. Berg discharged K.T. from Hope Clinic for violating her opioid treatment agreement by testing positive for cocaine. Mr. Berg wrote, "As of the receipt of this registered letter, you will not receive any more medicine prescriptions or refills from this office. This decision will not be reversed by appeal."
- 66. But, when K.T. appealed the decision, asking Mr. Berg in an email, "What would Jesus do?", and telling him, "Your [sic] turning a 100% Innocent person away for some false information," Mr. Berg relented, let her back into his practice, and continued to prescribe K.T. controlled substances.
- 67. In a subsequent urine drug test on February 28, 2019, K.T. tested positive for high levels of alcohol consumption, a dangerous combination with the opioids Mr. Berg prescribed her due to the fact that alcohol enhances the negative side effects of prescription opioids and can threaten an individual's health. Additionally, the use of alcohol violated K.T.'s opioid treatment agreement.
- 68. Despite the numerous red flags K.T. presented—traveling approximately 260 miles roundtrip to Hope Clinic, high doses of opioids well over the CDC Guidelines, high levels of alcohol consumption, violation of her opioid treatment agreement, and, most significantly,

evidence of illicit drug use—Mr. Berg continued to prescribe K.T. controlled substances, including the following prescriptions:

Written Date	Controlled Substance	Quantity
Feb. 28, 2019	Methadone Hcl 10 mg	120
Feb. 28, 2019	Methadone Hcl 10 mg	60
Feb. 28, 2019	Hydrocodone-Acetaminophen 10-325 mg	120
Feb. 28, 2019	Methylphenidate 20 mg	90
Feb. 28, 2019	Methadone Hcl 10 mg	120
Feb. 28, 2019	Methadone Hcl 10 mg	60
Feb. 28, 2019	Hydrocodone-Acetaminophen 10-325 mg	120
Feb. 28, 2019	Methylphenidate 20 mg	90
Apr. 25, 2019	Methadone Hcl 10 mg	120
Apr. 25, 2019	Methadone Hcl 10 mg	60
Apr. 25, 2019	Hydrocodone-Acetaminophen 10-325 mg	120
Apr. 25, 2019	Methylphenidate 20 mg	90
Apr. 25, 2019	Methylphenidate 20 mg	90
Apr. 25, 2019	Methadone Hcl 10 mg	60

Based on the unresolved red flags discussed above, Mr. Berg wrote each of these prescriptions without a legitimate medical purpose and outside of the usual course of professional practice.

#### D. Patient L.P.

- 69. L.P. was a sixty-three year old male patient from Muskegon when he first visited Mr. Berg at Hope Clinic on September 10, 2018, traveling approximately 260 miles roundtrip for this and subsequent visits with Mr. Berg.
- 70. Prior to visiting Hope Clinic, L.P. was a patient of Dr. Robertson, who treated him with high dosage levels of opioids (hydrocodone and methadone) to an average of 317 MME/day, dangerously combined with a prescription for carisoprodol.
- 71. Dr. Robertson's patient notes for L.P., which Mr. Berg acquired, contained a number of red flags (in addition to the high levels of opioids and concurrent prescribing of carisoprodol). For instance, Dr. Robertson's scant patient notes stated that L.P. preferred to alternate his pain medication "every year or so," evidence that the patient—rather than the

physician—was controlling the prescribing of medications. Additionally, Dr. Robertson's notes documented that L.P. was "non-compliant" on texting pictures of his pill count, a measure used to ensure that the patient is not diverting the prescribed medications or using them up too quickly.

- 72. Despite these initial red flags, Mr. Berg initially continued to prescribe L.P. hydrocodone, methadone, and carisoprodol (though he eventually stopped prescribing the carisoprodol). However, Mr. Berg did not have L.P. undergo a urine drug test for several months, contrary to the CDC Guidelines.
- 73. When L.P. finally took a urine drug test on January 4, 2019, he failed the test with a positive result for a benzodiazepine (oxazepam), a controlled substance he was not prescribed by Mr. Berg or any other practitioner. This positive result was a significant red flag. Not only did it show that L.P. was obtaining controlled substances from an illicit source, but the concurrent use of a benzodiazepine with the opioids Mr. Berg was prescribing was dangerous to L.P.'s health. Mr. Berg ignored this positive result in the subsequent patient notes for L.P. on March 4, 2019.
- 74. According to the MAPS report contained in L.P.'s patient file, as of March 1, 2019, L.P. was filling prescriptions for controlled substances at three different pharmacies, contrary to his opioid treatment agreement.
- 75. Despite the numerous red flags L.P. presented—traveling approximately 260 miles roundtrip to Hope Clinic, high doses of opioids well over the CDC Guidelines, breach of his opioid treatment agreement, and, most significantly, evidence of illicit drug use with potentially dangerous concurrent effects—Mr. Berg continued to prescribe L.P. controlled substances, including the following prescriptions:

Written Date	Controlled Substance	Quantity
Mar. 4, 2019	Methadone Hcl 10 mg	240
Mar. 4, 2019	Hydrocodone-Acetaminophen 10-325 mg	120
Mar. 4, 2019	Methadone Hcl 10 mg	240

Mar. 4, 2019	Hydrocodone-Acetaminophen 10-325 mg	120

Based on the unresolved red flags discussed above, Mr. Berg wrote each of these prescriptions without a legitimate medical purpose and outside of the usual course of professional practice.

## E. Patient L.W.

- 76. L.W. was a sixty-one year old male patient from Muskegon when he first visited Mr. Berg at Hope Clinic on September 10, 2018, traveling approximately 260 miles roundtrip for this and subsequent visits.
- 77. Prior to visiting Hope Clinic, L.W. was a patient of Dr. Robertson, who treated him with high dosage levels of opioids (hydrocodone and methadone) to an average of 290 MME/day, dangerously combined with prescriptions for carisoprodol.
- 78. Dr. Robertson's patient file for L.W., which Mr. Berg acquired, contained a number of red flags indicating that the controlled substance prescriptions written for L.W. were not for a legitimate medical purpose and were outside the usual course of professional practice. For instance, in addition to the dangerously high doses of prescribed opioids, Dr. Robertson's notes stated that L.W. was taking more hydrocodone in a day than Dr. Robertson had prescribed. Additionally, Dr. Robertson's patient file for L.W. showed that L.W. had failed multiple urine drug tests. Specifically, in May 2018, L.W. tested negative for the methadone and carisoprodol Dr. Robertson prescribed. Then, in July 2018, L.W. tested positive for the controlled substance buprenorphine that he had not been prescribed and negative again for carisoprodol that Dr. Robertson prescribed.
- 79. Despite these red flags, Mr. Berg prescribed L.W. the opioids hydrocodone and methadone at the same high dosage (290 MME/day) concurrently with carisoprodol (though Mr. Berg later stopped prescribing carisoprodol). Mr. Berg never performed an initial urine drug test

of L.W., inconsistent with the CDC Guidelines.

- 80. Then, in January 2019, Hope Clinic conducted a urine drug test of L.W., which L.W. failed, testing positive for buprenorphine that he was not prescribed. When Mr. Berg finally addressed this failed urine drug test in the patient notes for May 1, 2019, he noted that L.W. told him that "once or twice a year [L.W.] will use a couple of his sister's Suboxone [buprenorphine] that she is using for her heroin addiction treatment to decrease his methadone and opioid for several days to keep from getting tolerance." Mr. Berg documented that he warned L.W. that "[i]t is illegal to use or transfer medications that are prescribed from one person to another." Mixing buprenorphine with opioids can create a dangerous effect on patients. Illicit use of a controlled substance was also a violation of L.W.'s opioid treatment agreement.
- 81. Despite the numerous red flags L.W. presented—traveling approximately 260 miles roundtrip to Hope Clinic, high doses of opioids well over the CDC Guidelines, three failed urine drug tests, and, most significantly, patient admission of illicit drug use with potentially dangerous concurrent effects—Mr. Berg continued to prescribe L.W. controlled substances, including the following prescriptions:

Written Date	Controlled Substance	Quantity
May 1, 2019	Methadone Hcl 10 mg	240
May 1, 2019	Hydrocodone-Acetaminophen 10-325 mg	150
May 1, 2019	Methadone Hcl 10 mg	240
May 1, 2019	Hydrocodone-Acetaminophen 10-325 mg	150

Based on the unresolved red flags discussed above, Mr. Berg wrote each of these prescriptions without a legitimate medical purpose and outside of the usual course of professional practice.

# F. Patient C.B.

82. Patient C.B. was a forty-five year old female patient from Muskegon who reported being previously treated by Dr. Robertson. She traveled approximately 260 miles roundtrip to

visit Mr. Berg and for subsequent visits.

- 83. When Mr. Berg first met C.B. in October 2017, C.B. provided Mr. Berg with an inconsistent history of her controlled substance history over the prior few years.
- 84. C.B.'s patient records also contained records from another physician assistant who had discharged C.B. from her practice after C.B. failed a urine drug test in December 2017 by refusing to provide a urine sample.
- 85. Mr. Berg had C.B. take an initial urine drug test in October 2018, which she failed, testing positive for pregabalin (a controlled substance) and kratom (a highly-abused non-controlled substance).
- 86. Despite the red flags from C.B.'s failed urine drug test and history, Mr. Berg immediately prescribed C.B. hydrocodone at a dosage of 40 MME/day.
- 87. By December 2018, Mr. Berg started prescribing C.B. methadone in addition to the hydrocodone, taking her opioid dosage up to 130 MME/day, well above the CDC Guidelines.
- 88. In January 2019, C.B. failed another urine drug test, testing positive, again, for pregabalin that she was not prescribed by Mr. Berg or any other practitioner.
- 89. C.B. failed a follow-up urine drug test on March 2019, testing positive, again, for pregabalin.
- 90. According to the MAPS report contained in C.B.'s patient file, as of May 6, 2019, C.B. filled Mr. Berg's controlled substance prescriptions at four different pharmacies in the span of approximately six months.
- 91. Despite the numerous red flags C.B. presented—violating her opioid treatment agreement, traveling approximately 260 miles roundtrip to Hope Clinic, high doses of opioids well over the CDC Guidelines, and three failed urine drug tests along with a history of failing urine

drug tests—Mr. Berg continued to prescribe C.B. controlled substances, including the following prescriptions:

Written Date	Controlled Substance	Quantity
May 7, 2019	Methadone Hcl 10 mg	90
May 7, 2019	Hydrocodone-Acetaminophen 10-325 mg	120
June 5, 2019	Methadone Hcl 10 mg	90
June 5, 2019	Hydrocodone-Acetaminophen 10-325 mg	120

Based on the unresolved red flags discussed above, Mr. Berg wrote each of these prescriptions without a legitimate medical purpose and outside of the usual course of professional practice.

# COUNT I (Civil Penalties for Unlawful Prescribing of Controlled Substances)

- 92. The United States repeats and realleges Paragraphs 1 through 91 as if fully set forth herein.
- 93. Mr. Berg issued prescriptions without a legitimate medical purpose and outside the usual course of professional practice in violation of 21 U.S.C. §§ 829 and 842(a)(1) and 21 C.F.R. § 1306.04. These prescribing violations subject Mr. Berg to per-violation penalties of up to \$67,627.00 for violations that occurred after November 2, 2015. 21 U.S.C. §§ 842(a)(1), 842(c)(1)(A); 28 C.F.R. § 85.5.
- 94. As a result of the foregoing, Mr. Berg is liable to the United States for civil penalties in an amount to be proven at trial.

# COUNT II (Injunctive Relief)

- 95. The United States repeats and realleges Paragraphs 1 through 94 as if fully set forth herein.
- 96. As a result of the violations referred to in Count I, Mr. Berg is subject to injunctive relief pursuant to 21 U.S.C. §§ 843(f) and 882(a).

## **PRAYER FOR RELIEF**

WHEREFORE, the United States demands judgment in its favor and against Mr. Berg as follows:

- A. As to Count I, for a maximum statutory penalty in the amounts set forth above for each of the CSA violations set forth herein pursuant to 21 U.S.C. § 842;
  - B. As to Count II, entry of an order:
    - 1. Declaring that Mr. Berg violated the CSA, specifically 21 U.S.C. §§ 829 and 842(a)(1);
    - Permanently enjoining Mr. Berg from directly or indirectly distributing, dispensing, delivering, or prescribing any controlled substances as defined and identified in the CSA; and
    - Permanently enjoining Mr. Berg from applying or reapplying to DEA for a
      certificate of registration as a practitioner to prescribe and dispense any
      controlled substances.
  - C. For interest, attorneys' fees, and costs as allowed by law; and
  - D. For all such other and further relief as the Court may deem just and proper.

# **DEMAND FOR JURY TRIAL**

The United States hereby demands a trial by jury pursuant to Federal Rule of Civil Procedure 38.

Dated: August 9, 2020 Respectfully submitted,

ANDREW BYERLY BIRGE United States Attorney

/s/ Andrew J. Hull

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